

Advaxis, Inc.
Form 8-K
May 02, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **April 28, 2016**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware **000-28489** **02-0563870**

(State or Other Jurisdiction (Commission (IRS Employer
of Incorporation) File Number) Identification No.)

305 College Road East

Princeton, New Jersey, 08540

(Address of Principal Executive Offices)

(609) 452-9813

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act.
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- ☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Item 7.01 Regulation FD Disclosure.

A copy of the press release of Advaxis, Inc. (the “Company”) dated April 28, 2016 relating to the announcement discussed in Item 8.01 below is attached hereto as Exhibit 99.1.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On April 28, 2016, the Company announced that U.S. Food and Drug Administration had granted Fast Track Designation for the company’s immunotherapy product candidate ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. The FDA established the Fast Track Drug Development Program under the FDA Modernization Act of 1997. The program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to expedite development, including opportunities for frequent interactions with the FDA review team to discuss all aspects of development to support approval and eligibility for accelerated approval and priority review depending on clinical data at the time of Biologics License Application (BLA) submission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as a part of this report

99.1 Press Release dated April 28, 2016.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ADVAXIS, INC.
(Registrant)

By: */s/ Daniel J. O'Connor*
Daniel J. O'Connor
President and Chief Executive Officer

Date: May 2, 2016

INDEX TO EXHIBITS

Exhibit

Number Description

99.1 Press Release dated April 28, 2016.

